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Appln. No. : 09/897,295
Applicant : William J. Boyle et al.
Filed : June 29, 2001
Title : DELIVERY AND RECOVERY SHEATHS
FOR MEDICAL DEVICES
Art Unit : 3743
Examiner : Mitchell, Teena Kay

Docket No.: : ACSES 56001 (2636P) Los Angeles, California
Customer No. : 24201 July 24, 2007

RESPONSE TO NOTICE OF NON COMPLIANT APPEAL BRIEF

Mail Stop Appeal Brief - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This is in response to the Notice of Non Compliant Appeal Brief dated July 19, 2007 of which Response is due August 18, 2007.

This Appeal Brief is responsive to the Notice of Panel Decision from Pre-Appeal Brief Review dated May 10, 2007. This Appeal Brief is being filed in accordance with 37 C.F.R. § 41.37 and is being filed within one month of the mailing of the Panel's Decision. A Notice of Appeal was filed on March 2, 2007.

INTRODUCTION

The present invention is directed to delivery and recovery sheaths for use with medical devices which deliver self-expanding medical devices, such as stents and vascular grafts, for implantation in a patient's vasculature. The present invention can be used with other medical devices, such as an embolic filtering device, which generally includes a self-expanding filter basket disposed on a guide wire. The restraining device of the present invention can be used to deliver the filtering device or stent

to the target location in the patient's anatomy and/or to collapse and retrieve the filtering device once the interventional procedure has been completed.

The restraining device includes a restraining sheath having an expandable housing portion adapted to collapse and hold the self-expanding medical device. The expandable housing portion is made from an elastic material to hold the medical device in place and prevent premature deployment. The housing portion of the sheath acts to "encapsulate" the medical device, thus preventing it from being released from the sheath until the physician is ready to do so. When the present invention is utilized as a recovery sheath to recover a filtering device, the housing portion will contract to its smallest diameter as it tracks along the guide wire to reach the embolic filtering basket. As a result, the tip of the sheath should not scrape the walls of the body vessel causing a "snowplow" effect as the sheath is being advanced over the guide wire. Once the filtering basket is retrieved, the elasticity of the housing portion encapsulates the basket to prevent emboli trapped in the basket from "back washing" into the patient's vasculature.

The expandable housing portion includes one or more reinforcing members that provide additional column strength to the housing portion but do not interfere with the radial expansion or contraction of the elastic housing. These reinforcing members provide additional column strength which permits the housing portion to be made from a highly elastic material that would otherwise buckle when subjected to an applied axial force. Various configurations of this reinforcing member are recited in the dependent claims.

The present application, U.S. Serial No. 09/897,295, was filed on June 29, 2001. A Notice of Appeal was filed on January 24, 2007. This Appeal Brief is being filed in accordance with 37 C.F.R. § 41.37 and is being filed within one month of the mailing of the Panel's Decision.

REQUEST FOR ORAL ARGUMENT

An oral argument is requested.

I. REAL PARTY IN INTEREST

The real party in interest is ABBOTT VASCULAR, Inc., Santa Clara, California, as owner of the rights originally assigned to ADVANCED CARDIOVASCULAR SYSTEMS, INC. This application was originally assigned by the inventors, WILLIAM J. BOYLE, ANDY E. DENNISON,

BENJAMIN C. HUTER, SCOTT J. HUTER, JOHN E. PAPP, CHARLES R. PETERSON and KENT C. B. STALKER to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment executed on June 26, 2001 which was recorded by the Patent Office on June 29, 2001 beginning at Reel 011971, Frame 0220.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

This patent application has pending claims under consideration. Pending claims 3-13, 20-26 and 41-51 were finally rejected in a final Office Action dated October 24, 2006.

Claims 3-13, 20-26 and 41-51 are pending in the application and the rejection of claims 3-13, 20-26 and 41-51 is being appealed. Original claims 1, 2 and 33-40 have been canceled without prejudice. Claims 14-19 and 27-32 have been withdrawn from prosecution in view of an election of species requirement. A copy of the appealed claims is attached hereto as Exhibit 1.

Claims 3-13, 20-26 and 41-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,544,279 to Hopkins et al. (the "Hopkins patent") in view of U.S. Patent No. 6,123,715 to Amplatz (the "Amplatz patent") and U.S. Patent No. 6,517,765 to Kelley (the "Kelley patent").

A copy of the Hopkins patent is attached hereto as Exhibit 2. A copy of the Amplatz patent is attached hereto as Exhibit 3 and a copy of the Kelley patent is attached as Exhibit 4.

IV. STATUS OF AMENDMENTS

Office Action Dated April 29, 2004 (a copy of which is attached as Exhibit 5)

In an Office Action dated April 29, 2004 the Examiner:

- issued an election of species requirement to the pending claims.

Response Dated June 1, 2004 (a copy of which is attached as Exhibit 6)

In a Response dated June 1, 2004, Applicant:

- Elected the invention directed to the Species of FIGS. 1-3, 4-5 and 14-16 and withdrew claims 14-19 and 27-40 from prosecution.

Office Action Dated August 27, 2004 (a copy of which is attached as Exhibit 7)

In an Office Action dated August 27, 2004, the Examiner:

- rejected claims 1, 2 and 20 under 35 U.S.C. § 102(e) as being anticipated by the Hopkins patent; and
- rejected claims 3-13 and 21-26 22 under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of U.S. Patent No. 6,544,279 to Cryer (the "Cryer patent").

Amendment Dated November 29, 2004 (a copy of which is attached as Exhibit 8)

In an Amendment Dated November 29, 2004, Applicant:

- canceled without prejudice claims 1 and 2;
- re-wrote dependent claim 3 in independent form;
- added new claims 41-51; and
- presented arguments to overcome the rejections based on the Hopkins patent and the combination of the Hopkins patent and the Cryer patent.

Office Action Dated February 24, 2005 (a copy of which is attached as Exhibit 9)

In an Office Action dated February 24, 2005, the Examiner:

- withdrew the previous rejections of claims 3-13 and 21-26 under 35 U.S.C. § 103(a);
- and
- rejected claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent.

Amendment dated May 20, 2005 (a copy of which is attached as Exhibit 10)

In an Amendment dated May 20, 2005, Applicant:

- amended independent claim 3 to include the recitation that reinforcing member does not interfere with the expansion of the housing portion; and
- presented arguments to overcome the rejections under 35 U.S.C. § 103(a).

Final Office Action Dated September 29, 2005 (a copy of which is attached as Exhibit 11)

In a final Office Action dated September 29, 2005, the Examiner:

- rejected claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent and in further view of the Kelley patent.

Amendment After Final Dated November 29, 2005 (a copy of which is attached as Exhibit 12)

In an Amendment After Final dated November 29, 2005, Applicant:

- amended independent claim 3 to include the recitation that reinforcing member is non-woven; and
- presented arguments to overcome the rejections under 35 U.S.C. § 103(a).

Advisory Action Dated December 21, 2005 (a copy of which is attached as Exhibit 13)

In an Advisory Action dated December 21, 2005, the Examiner refused entry of the Amendment After Final dated November 29, 2005 on the grounds that the amendment raised new issues and required a new search.

RCE Dated December 29, 2005 (a copy of which is attached as Exhibit 14)

In an RCE dated December 29, 2005, Applicant resubmitted the previously presented Amendment.

Office Action Dated March 20, 2006 (a copy of which is attached as Exhibit 15)

In an Office Action dated March 20, 2006, the Examiner:

- again rejected claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent and in further view of the Kelley patent.

Amendment Dated June 16, 2006 (a copy of which is attached as Exhibit 16)

In an Amendment dated June 16, 2006, Applicant:

- amended claims 3 and 41 to clarify that the reinforcing member does not interfere with the expansion or contraction of the housing portion; and
- presented arguments to overcome the rejections under 35 U.S.C. § 103(a).

Final Office Action Dated September 11, 2006 (a copy of which is attached as Exhibit 17)

In a final Office Action dated October 24, 2006, the Examiner:

- maintained the rejection of claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent and in further view of the Kelley patent.

Amendment After Final Dated November 8, 2006 (a copy of which is attached as Exhibit 18)

In an Amendment After Final dated November 8, 2006, Applicant:

- amended independent claim 3 to delete the recitation that reinforcing member is non-woven; and
- presented arguments to overcome the rejections under 35 U.S.C. § 103(a).

Advisory Action Dated January 4, 2007 (a copy of which is attached as Exhibit 19)

In an Advisory Action dated January 4, 2007, the Examiner entered the Amendment After Final dated November 8, 2006 for purposes of appeal.

Notice of Appeal Dated March 2, 2007 (a copy of which is attached as Exhibit 20)

A Notice of Appeal dated March 2, 2007 was filed by the Applicant.

Pre-Appeal Brief Request for Review Dated March 2, 2007 (a copy of which is attached as Exhibit 21)

In a Pre-Appeal Brief Request for Review Dated March 2, 2007, the Applicant:

- presented argument to overcome the rejections under 35 U.S.C. § 103(a).

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to delivery and recovery sheaths for use with medical devices which deliver self-expanding medical devices, such as stents and vascular grafts, for implantation in a patient's vasculature. The restraining device includes a restraining sheath having an expandable housing portion adapted to collapse and hold the self-expanding medical device. The expandable housing portion is made from an elastic material to hold the medical device in place and prevent premature deployment. The housing portion of the sheath acts to "encapsulate" the medical device, thus preventing it from being released from the sheath until the physician is ready to do so. When the present invention is utilized as a recovery sheath to recover a filtering device, the housing portion will contract to its smallest diameter as it tracks along the guide wire to reach the embolic filtering basket. As a result, the tip of the sheath should not scrape the walls of the body vessel causing a "snowplow"

effect as the sheath is being advanced over the guide wire. Once the filtering basket is retrieved, the elasticity of the housing portion encapsulates the basket to prevent emboli trapped in the basket from "back washing" into the patient's vasculature.

The expandable housing portion includes one or more reinforcing members that provide additional column strength to the housing portion but do not interfere with the radial expansion or contraction of the elastic housing. These reinforcing members permits the housing portion to be made from a highly elastic material that could possible buckle when subjected to an applied axial force.

Independent claim 3 is supported by at least the following references to the specification, reference characters, and figures:

3. A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath (page 11, lines 10-20, FIGS. 1-3, # 22; page 14, lines 8-14, FIGS. 4-5, # 64; page 15, lines 20-27, FIGS. 6-7, # 78) having an expandable housing portion (page 11, lines 10-20, FIGS. 1-3, # 22; page 14, lines 8-17, FIGS. 4-5, # 62; page 15, lines 20-23, FIGS. 6-7, # 76) adapted to receive and maintain the self-expanding medical device (page 11, lines 10-20, FIGS. 2 and 16, # 34) in a collapsed condition on the delivery device (page 11, lines 10-20, FIGS. 2 and 16, #38), the expandable housing portion being adapted to move between a contracted position (FIGS. 4 and 6) and expanded position (FIGS. 5 and 7), the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material (page 14, lines 8-24, FIGS. 4-5, # 66; page 15, lines 20-25, FIGS. 6-7, # 82) which is movable between the contracted position and expanded position and includes at least one reinforcing member (page 14, lines 8-21, FIGS. 4-5, # 68; page 15, lines 20-32, FIGS. 6-7, # 80) associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion (page 15, line 33-page 16, line 1).

Independent claim 41 is supported by at least the following references to the specification, reference characters, and figures:

41. A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath (page 11, lines 10-20, FIGS. 1-3, # 22; page 14, lines 8-14, FIGS. 4-5, # 64; page 15, lines 20-27, FIGS. 6-7, # 78) having an expandable housing portion page 11, lines 10-20, FIGS. 1-3, # 22; page 14, lines 8-17, FIGS. 4-5, # 62; page 15, lines 20-23, FIGS. 6-7, # 76) adapted to move between a contracted position (FIGS. 4 and 6) and an expanded position (FIGS. 5 and 7) and to maintain the self-expanding medical device (page 11, lines 10-20, FIGS. 2 and 16, # 34) in a collapsed condition on the delivery device (page 11, lines 10-20, FIGS. 2 and 16, #38), and a reinforcing member (page 14, lines 8-21, FIGS. 4-5, # 68; page 15, lines 20-32, FIGS. 6-7, # 80), associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions (page 15, line 33-page 16, line 1).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the final Office Action dated September 11, 2006, the Examiner rejected claims 3-13, 20-26 and 41-51 as being unpatentable under 35 U.S.C. § 103(a) over the Hopkins patent in view of the Amplatz patent and the Kelley patent

In view of the Examiner's rejections, Appellant respectfully submits that the sole issue on appeal is as follows:

Issue 1. Are claims 3-13, 20-26 and 41-51 unpatentable under 35 U.S.C. § 103(a) over the Hopkins patent in view of the Amplatz patent and the Kelley patent.

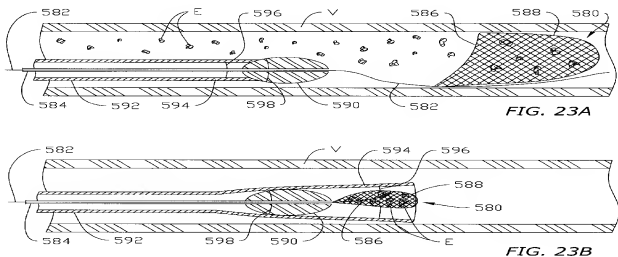
VII. ARGUMENT

Issue 1.

Claims 3-13, 20-26 and 41-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent and the Kelley patent. The Hopkins patent discloses a retrieval sheath including an expandable housing portion used to retrieve a filter. The Examiner has taken the position that the Hopkins patent discloses a housing portion made primarily from an elastic material which is movable between a contracted position and expanded position, but

has admitted that the Hopkins patent fails to disclose a reinforcing member which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion. All of the pending claims include the recitation of a reinforcing member. The Examiner relies on the embodiment of Figures 23A and 23B in the Hopkins patent as the primary reference. First, it is noted that the retrieval sheath **592** and expandable end region **594** (the housing portion) of the Hopkins device already possesses sufficient column strength as evidenced when the expander **590** moves into the end region **594** to radially expand it in order to form a larger opening to retrieve the filter **580**.

Figures 23A and 23B of the Hopkins patent, relied upon by the Examiner in rejecting the pending claims, are reproduced herein.



Reference is initially made to Figure 23B of the Hopkins patent which clearly shows that the distal end region **594** of the retrieval sheath **592** remains "unbunched" after being radially stretched by the expander **590**. The end region **594** of the retrieval sheath **592** must possess sufficient column strength in order to allow the expander **590** to move within the opening to radially expand the tubing. Otherwise, if the end region **594** did not possess enough column strength, then the end region **594** would "bunch" upon itself, much like the bellows of an accordion, when the expander **590** contacts the end region **594** and applies an axial force.

The Hawkins patent thus fails to disclose the use or need for **any** reinforcing member with its housing since the housing already has sufficient column strength to retrieve the filter **580**. The sheath **592** already possess sufficient column strength as evidenced by the expander's ability to

radially expand the end region **594** **without** causing bunching. If the end region 594 did not possess sufficient column strength, then the expander **590** would crush the tubing longitudinally as the expander **590** is drawn into the end region **594**. Therefore, one skilled in the art would **see no need or reason** to increase the column strength of the Hopkins retrieval sheath **592** with any type of reinforcing member.

Figure 23B of the Hopkins patent also shows that the distal end region **594** of the retrieval sheath **592** does not move **between** a contracted position and an expanded condition as recited in claims 3 and 41. Rather, the distal end region **594** only moves **from** a contracted position to an expanded position as is depicted in Figures 23A and 23B above. Once the distal end region **594** is moved into the expanded position by the expander **590**, it remains fully expanded as depicted in Figure 23B. It does not move back to the collapsed position since it appears that the distal end region **594** has been plastically deformed into the expanded position. If the distal end region **594** were capable of moving between expanded and collapsed positions, then the distal end region **594** would be in contact with the filter **586**. This disclosure further supports Appellant's position that the retrieval sheath **592** of the Hopkins patent is sufficiently strong such that reinforcing members would not be needed to provide any additional strength.

As stated above, the Examiner has admitted that the Hopkins patent fails to disclose a reinforcing member which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion. The Examiner stated the following in the Final Office Action dated September 29, 2005 (Exhibit 11):

The difference between Hopkins and claim 3 is a reinforcing member associate therewith which provides additional column strength to the housing portion but does not interfere with the expansion of the housing portion. (page 4, lines 7-9).

The Examiner relies on two patents, the Amplatz patent and the Kelley patent, to supply the missing element from the Hopkins patent. However, the Amplatz patent simply discloses a method for forming intravascular devices using resilient metal fabric. The Examiner relies on an innocuous statement appearing in the Amplatz patent that describes the metal fabric used in the Amplatz method as being a tubular braid that has been used in the medical device field to reinforce the walls of guiding catheters. That statement in the Amplatz patent reads as follows:

In the fabric of FIG. 1A, the metal strands define two sets of essentially parallel generally helical strands, with the strands of one set having a "hand", i.e. a direction of rotation,

opposite that of the other set. This defines a generally tubular fabric, known in the fabric industry as a tubular braid. **Such tubular braids are well known in the fabric arts and find some applications in the medical device field as tubular fabrics, such as in reinforcing the wall of a guiding catheter. As such braids are well known, they need not be discussed at length here.** (Exhibit 3, Column 3, lines 39-48, emphasis added).

However, as will be discussed in greater detail below, this statement appearing in the Amplatz patent and its disclosure simply fails to provide the missing elements from the Hopkins patent.

The Kelley patent provides even less support for the Examiner's position. The Kelley patent is merely directed to a method for fabricating flexible and reinforcing tubing and simply teaches that the pitch and/or braid pick counts of the woven fabric and braid can be selected to affect the flexibility of the tubing into which they are formed. The Examiner has taken the position that it would have been obvious to modify the expandable housing portion of the Hopkins device by adding the woven braids disclosed in the Amplatz and Kelley patents. However, Appellant submits that the housing portion disclosed in the Hopkins patent, as discussed above, already possesses sufficient column strength and that there would be no need or reason to utilize reinforcing members to increase column strength of the tubing used to form the housing.

Even assuming *arguendo* that one would still want to increase the column strength of the Hopkins sheath 584, claims 3 and 41 require the reinforcing member to increase the column strength of the housing portion **without** interfering with the expansion or contraction of the housing portion. The Amplatz patent simply states that tubular braids have been used to reinforce the walls of a guiding catheter. Guiding catheters are generally designed to be laterally flexible and will revert to a pre-formed shape once inserted in a patient's vasculature. In this regard, a guiding catheter will be inserted into the patient's vasculature in a relative linear configuration and will then revert to its pre-formed shape after reaching its target location. While this structure may require lateral flexibility along the length of the guiding catheter, it does not require the ability to expand or collapse, since the tubular structure of the guiding catheter is not designed to expand or collapse radially. For this reason, tubular braids have been used to reinforce the wall of the guiding catheter since the intertwining braid geometry is designed to inhibit expansion and collapse, but will allow the needed lateral or longitudinal flexibility. Simply put, the use of a woven braid with an expandable housing would inhibit radial contraction and expansion of the housing.

The sheath in the Hawkins patent is designed to radially expand as it contacts the expander. However, a woven braid placed on or into an expandable sheath would inhibit the sheath from expanding

or contracting radially. Thus, the tubular braid of the Amplatz patent would inhibit expansion of the sheath. The Kelley patent merely teaches that the pitch and/or braid pick counts of the woven braid can be selected to affect the **flexibility** of the tubing into which they are formed. Therefore, lateral flexibility can be changed. However, woven braids or fabrics described in the Amplatz and Kelley patents would still inhibit **expansion** or **collapse** of the elastic tubing. Therefore, while one can increase or decrease the lateral flexibility of the tubing by varying the pitch or braid count, as taught by the Amplatz and Kelley patents, the woven braid or fabric will still inhibit expansion and collapse of the tubing. Therefore, the combination of the Hopkins patent with the Amplatz and Kelley patent simply fails to create the structure recited in the pending claims.

In summation, the Hopkins patent fails to disclose the basic elements recited in the pending claims. Moreover, one skilled in the art would be no need or reason to add reinforcing members to the particular sheath disclosed in the Hopkins patent. The Amplatz and Kelley patents only disclose structure which would inhibit expansion and collapse of the housing portion. Thus, the suggested combination of these patents would not create the structure recited in the pending claims.

CONCLUSION

For the foregoing reasons, it is submitted that the present invention as claimed is not unpatentable over the Hopkins patent in view of the Amplatz and Kelley patents and the Examiner's rejection of claims 3-13, 20-26 and 41-51 was erroneous.

VIII. CLAIMS APPENDIX

PLEASE SEE EXHIBIT 1.

IX. EVIDENCE EXHIBIT

<u>EXHIBIT</u>	<u>DESCRIPTION</u>
1.	Appealed Claims.
2.	U.S. Patent No. 6,544,279 to Hopkins et al.
3.	U.S. Patent No. 6,123,715 to Amplatz.
4.	U.S. Patent No. 6,517,765 to Kelley (the "Kelley patent").
5.	Office Action Dated April 29, 2004.
6.	Response Dated June 1, 2004.

<u>EXHIBIT</u>	<u>DESCRIPTION</u>
7.	Office Action Dated August 27, 2004.
8.	Amendment Dated November 29, 2004.
9.	Office Action Dated February 24, 2005.
10.	Amendment dated May 20, 2005.
11.	Final Office Action Dated September 29, 2005.
12.	Amendment After Final Dated November 29, 2005.
13.	Advisory Action Dated December 21, 2005.
14.	RCE Dated December 29, 2005.
15.	Office Action Dated March 20, 2006.
16.	Amendment Dated June 16, 2006.
17.	Final Office Action Dated September 11, 2006.
18.	Amendment After Final Dated November 8, 2006.
19.	Advisory Action Dated January 4, 2007.
20.	Notice of Appeal Dated March 2, 2007.
21.	Pre-Appeal Brief Request for Review Dated March 2, 2007.

X. RELATED PROCEEDINGS EXHIBIT

None.

In the event there are any further charges associated with the filing of the subject Appeal Brief, the Director of Patents and Trademarks is hereby authorized to charge our Deposit Account No. 06-2425.

Respectfully submitted,

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CLAIMS ON APPEAL:

1-2. (Canceled)

3. (Previously Presented) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to receive and maintain the self-expanding medical device in a collapsed condition on the delivery device, the expandable housing portion being adapted to move between a contracted position and expanded position, the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material which is movable between the contracted position and expanded position and includes at least one reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion.

4. (Previously Presented) The restraining device of claim 3, further including:
a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion.

5. (Previously Presented) The restraining device of claim 4, wherein:
the reinforcing members extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material.

6. (Previously Presented) The restraining device of claim 5, wherein:
the reinforcing members are elongated bar-like members made from a material having high stiffness.

7. (Original) The restraining device of claim 3, wherein:
the elastic material is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX.

8. (Previously Presented) The restraining device of claim 4, wherein:
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
9. (Previously Presented) The restraining device of claim 8, wherein:
the reinforcing members are loaded with a material having high radiopacity.
10. (Previously Presented) The restraining device of claim 3, wherein:
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
11. (Previously Presented) The restraining device of claim 4, wherein:
the reinforcing members are disposed within the elastic material forming the expandable housing portion.
12. (Previously Presented) The restraining device of claim 4, wherein:
the reinforcing members are attached to the surface of the expandable housing portion.
13. (Previously Presented) The restraining device of claim 4, wherein:
each reinforcing member is disposed along the expandable housing portion to provide additional column strength to the housing portion but does not interfere with the expansion of the housing portion.
- 14-19. (Withdrawn)
20. (Previously Presented) The restraining device of claim 3, wherein:
the expandable housing portion includes a low expansion section with at least one expansion member disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position.

21. (Previously Presented) The restraining device of claim 3, wherein:
the expandable housing portion includes a plurality of low expansion sections and
a plurality of expansion members disposed between low expansion sections.

22. (Original) The restraining device of claim 21, wherein:
the low expansion sections are made from a material loaded with a material
having high radiopacity.

23. (Original) The restraining device of claim 21, wherein:
the expansion members are made from an elastic material selected from a group
which includes polyurethane, silicone, polyisoprene and lower durometer PEBAX.

24. (Original) The restraining device of claim 23, wherein:
the low expansion sections are made from a material selected from a group
including cross-linked HDPE, polyolefin and polyamide.

25. (Original) The restraining device of claim 21, wherein:
the expansion members extend longitudinally along the length of the expandable
housing portion.

26. (Original) The restraining device of claim 25, wherein:
the expansion members include means for preventing the low expansion sections
from tearing as the expandable housing portion expands from the contracted position to the
expanded position.

27-32. (Withdrawn)

33-40. (Canceled)

41. (Previously Presented) A restraining device for maintaining a self-expanding
medical device on a delivery device, comprising:
a restraining sheath having an expandable housing portion adapted to move
between a contracted position and an expanded position and to maintain the self-expanding

medical device in a collapsed condition on the delivery device, and a reinforcing member associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions.

42. (Previously Presented) The restraining device of claim 41, further including:
a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion but which do not interfere with the ability of the expandable housing to move between the contracted and expanded positions.

43. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is embedded in the wall which forms the expandable housing portion.

44. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is an elongated bar-like member made from a material having a stiffness higher than the stiffness of the material used to form the expandable housing portion.

45. (Previously Presented) The restraining device of claim 41, wherein:
the expandable housing portion is made from an elastic material selected from a group of materials which includes silicone, polyurethane, polyisoprene, and low durometer PEBAX.

46. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.

47. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is loaded with a material having high radiopacity.

48. (Previously Presented) The restraining device of claim 41, wherein:

the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.

49. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is molded within the material used to form the expandable housing portion.

50. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member is attached to the surface of the expandable housing portion.

51. (Previously Presented) The restraining device of claim 41, wherein:
the reinforcing member helps to bias the expandable housing portion in the contracted position.

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